DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

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MEDICARE NEWS

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MEDICARE PROPOSAL WILL HELP STANDARDIZE COVERAGE DECISIONS FOR ADDITIONAL TREATMENTS

The Health Care Financing Administration issued a *Federal Register* notice today proposing to develop national standards to help guide coverage decisions for more than 39 million people in Medicare.

"This is a major step forward for Medicare, and for the millions of Americans who rely on Medicare for health care coverage," said HCFA Administrator Nancy-Ann DeParle. "The process we are launching today will help establish the most open, timely and dependable system possible for making national Medicare coverage decisions."

The notice of intent was put on display at the *Federal Register* office today. It will be published in the *Federal Register* on May 16.

A coverage criteria rule will be the latest step in HCFA's ongoing efforts toward a more open, understandable and predictable process for making Medicare coverage decisions. Last year, HCFA adopted a new administrative process for coverage decisions and created a Medicare Coverage Advisory Committee to bring private sector expertise into the process.

The notice of intent is the first step in a rule-making process that will lead to the first national criteria for what is "reasonable and necessary," the standard required by law before expenses incurred for an item or service can be covered by Medicare. The notice invites public comment, which may be received for 30 days following publication of today's notice. Public comments will be considered in the drafting of proposed and rules. The public will then have an additional opportunity to comment on the criteria before they are finalized.

Under the framework provided by Medicare law, most coverage decisions are made at the local level by the private insurance companies -- called carriers or fiscal intermediaries -- that process and pay Medicare claims. These decisions are binding only in the local area covered by each contractor. HCFA has the authority to make national coverage decisions, which are binding on all contractors and the administrative law judges who hear Medicare appeals in the administrative process.

When the coverage criteria initiated by today's notice are put into effect, they will govern national coverage decisions. And carriers and fiscal intermediaries will use these principles in making local decisions.

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Medicare law requires that in order for expenses incurred for items or services to be covered, they must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning or a malformed body member."

Working within those parameters, Medicare coverage decisions have been made on case-by-case interpretations of what is reasonable and necessary. But experience has shown that a standardized national definition of these criteria is needed for more consistent and timely decision making and to expand access to appropriate new technologies for Medicare beneficiaries.

HCFA's notice of intent describes two criteria that would be applied in making national coverage decisions. First, an item or service must be shown to have medical benefit, and, second, it must demonstrate added value to people in Medicare.

- An item or service is medically beneficial if objective clinical evidence shows it produces a health outcome better than the natural course of illness or disease with customary medical management of symptoms. Under current coverage policy it already would be considered not to be reasonable and necessary to pay for expenses incurred for items or services that are not proven to be effective for a defined population.

  The notice also says that HCFA should move towards "quality of life" as an acceptable health outcome.

- Added value would be measured in a several ways. An item or service might add value to existing coverage if it substantially improves health outcome. Or it could provide access to a medically beneficial treatment of a different type -- for example, medication instead of surgery. Another consideration could be whether it could be substituted for an existing treatment at lower cost to the Medicare population.

In general, cost would not be considered in making a coverage decision if a new item or service would be medically beneficial and there is no Medicare-covered alternative available. Cost also would not be a consideration when a new item or service would be medically beneficial and is a different clinical type than a Medicare-covered one -- such as a covered medication or surgery versus some other type of treatment. But cost limits could be applied for more expensive items or services that did not have significant added medical benefit to the patient.

Coverage criteria are key to HCFA's continuing effort to make its coverage process more open, understandable, predictable and timely. The criteria, when they become final, will provide the third step in a four-step strategy begun last year.

The first step was creation of a new administrative process for coverage decisions. It outlines how the public may request national coverage decisions, time lines for reviewing requests, and the major scientific questions that need to be resolved before a decision can be made. The status of each pending coverage decision is posted on HCFA's web site, *www.hcfa.gov.* Secondly, HCFA created the Medicare Coverage Advisory Committee to bring the best outside experts and latest scientific evidence to the process.

The final step will be the creation of service-specific guidance documents to supplement the final criteria rule. While we expect the coverage criteria would apply to all items and services, HCFA anticipates that guidance documents will be needed to explain how the rules apply to specific health care services such as diagnostic labs, radiology tests, surgical procedures, biologics, and durable medical equipment.

Medicare is committed to having an open, understandable and predictable coverage process for the benefits it provides. The Medicare law provides broad coverage for many medical and health care services, including care provided by hospitals, skilled-nursing facilities, home-health agencies and physicians. The law does not specify which medical devices, surgical procedures or diagnostic services should be included or excluded from coverage. It authorizes the Health and Human Services Secretary to decide which specific expenses incurred for items and services within these categories are "reasonable and necessary" and can be covered.

"Medicare's new process for making coverage decisions will be the most open and accountable process in Medicare history," DeParle said. "And Medicare beneficiaries deserve no less."

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